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(54) **BRACHYTHERAPY DEVICE FOR ASYMMETRICAL IRRADIATION OF A BODY CAVITY**

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CPC *A61N 5/1015* (2013.01); *A61N 2005/1005* (2013.01); *A61N 2005/1018* (2013.01)

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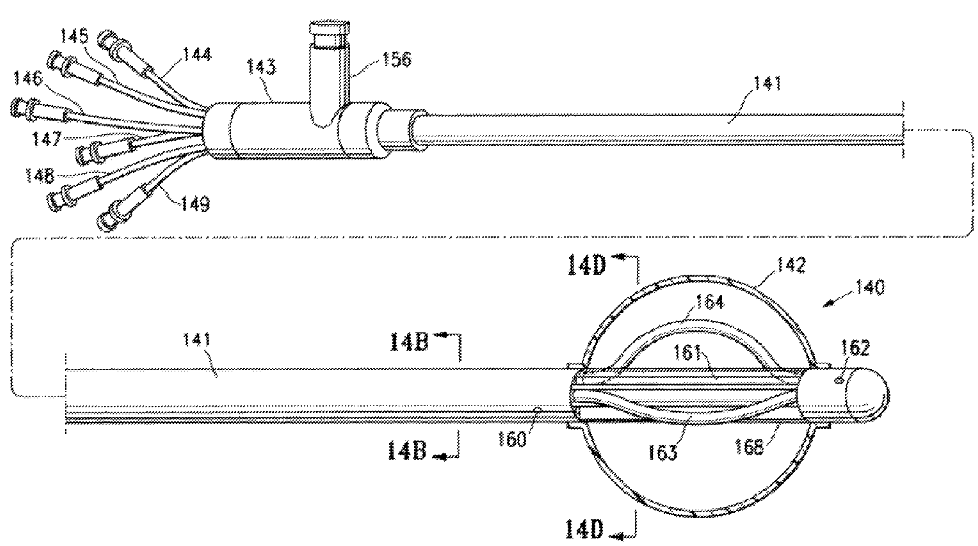
(57) **ABSTRACT**

The disclosure describes devices and methods for asymmetrical irradiation at a body cavity or site, such as after removal of tissue, e.g. biopsy or cancer. One device includes a lumen which is off-set or off-settable from a longitudinal axis to increase the intensity of radiation received from a radiation source by a first tissue portion surrounding the body cavity and to reduce or minimize radiation received by a second tissue portion (e.g. healthy tissue) surrounding the body cavity.

20 Claims, 6 Drawing Sheets



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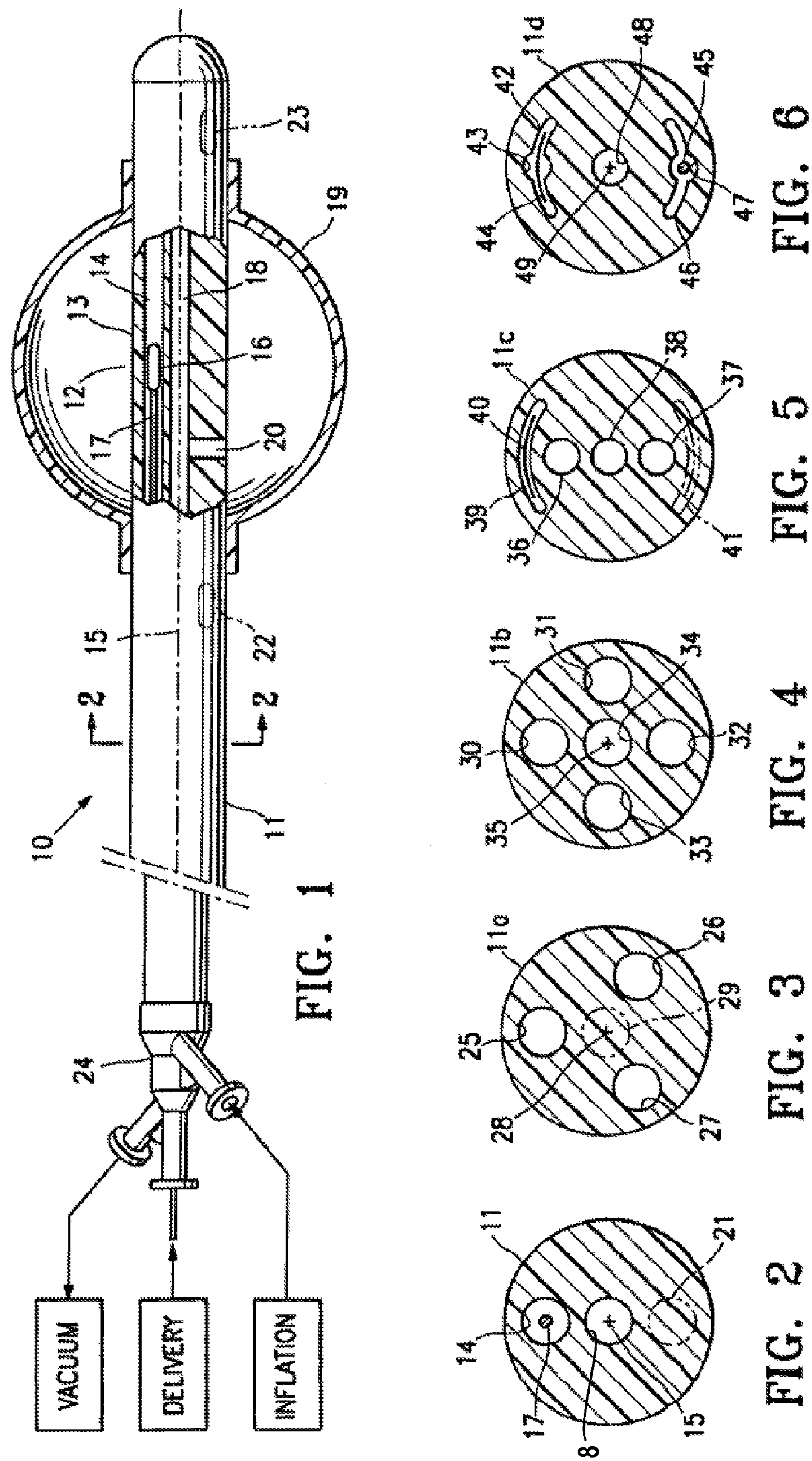

FIG. 1

FIG. 2

FIG. 3

FIG. 4

FIG. 5

FIG. 6

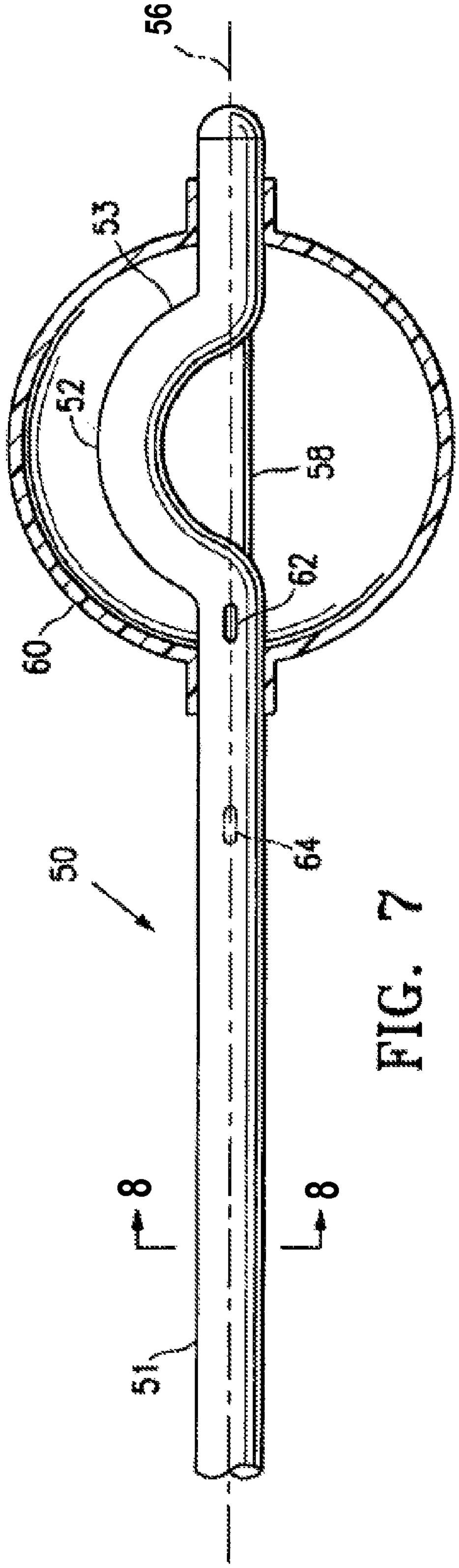

FIG. 7

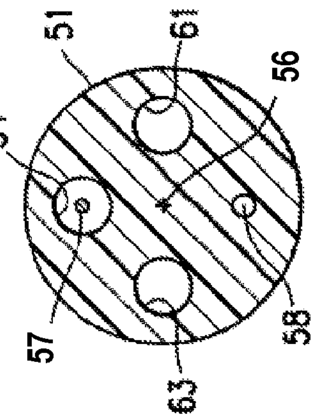

FIG. 8

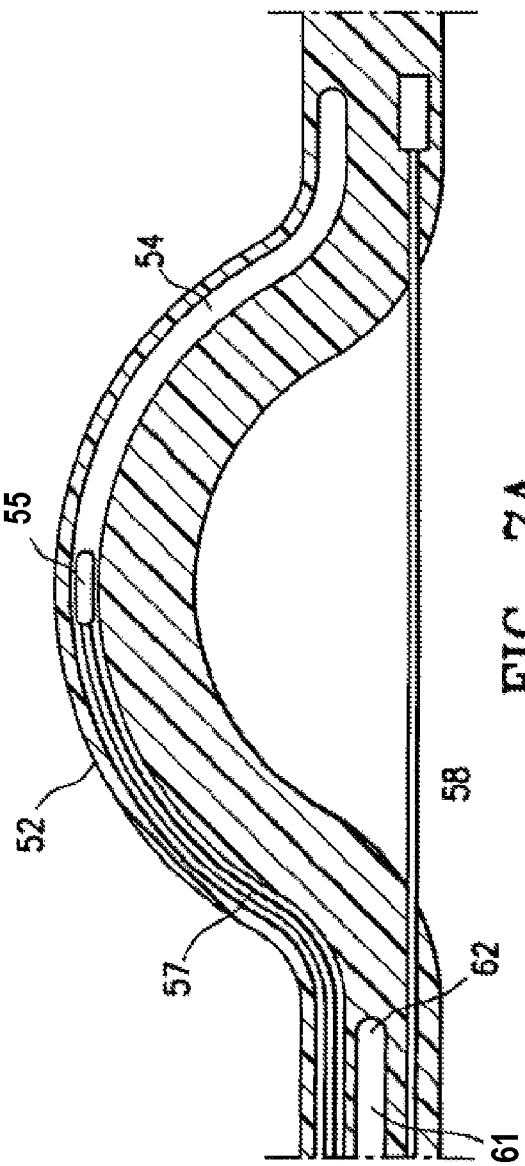

FIG. 7A

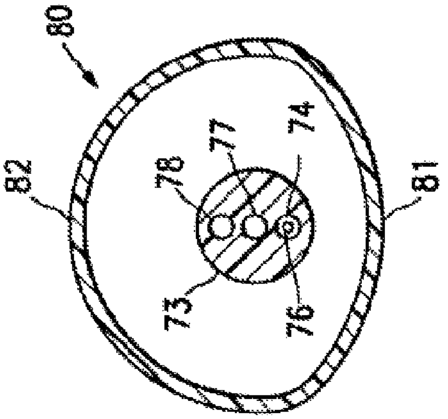

FIG. 10

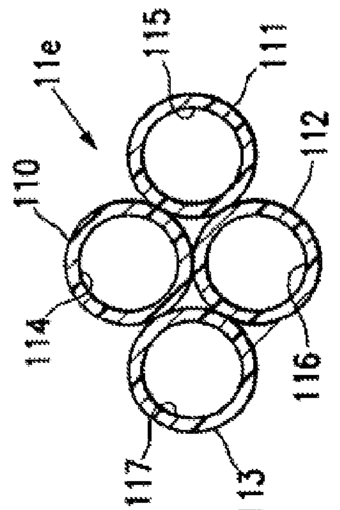

FIG. 12

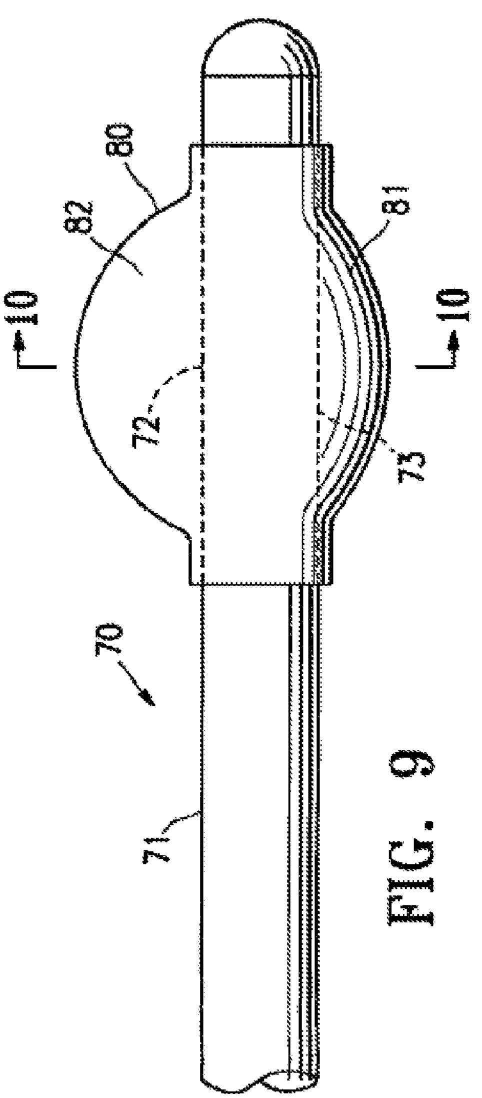

FIG. 9

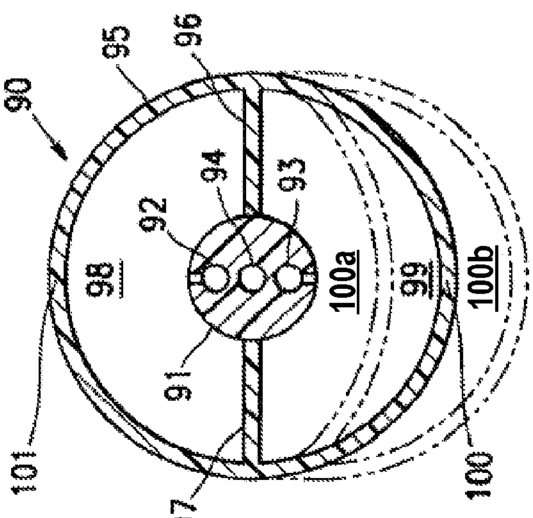

FIG. 11

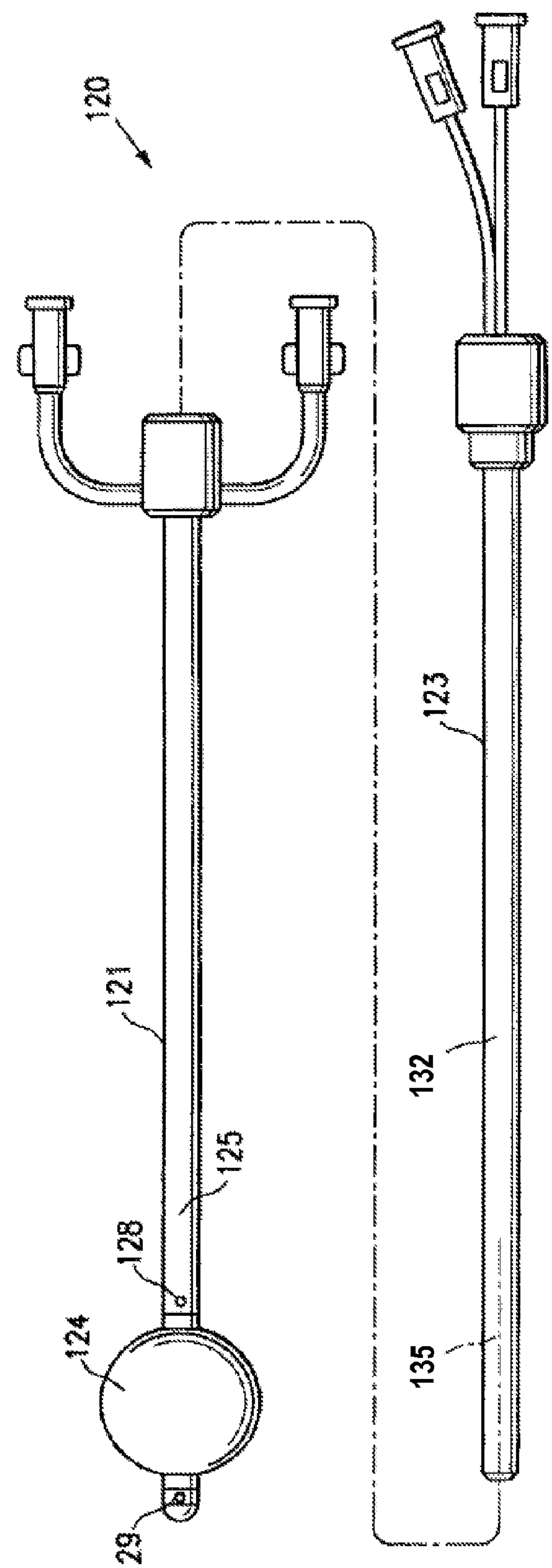

FIG. 13A

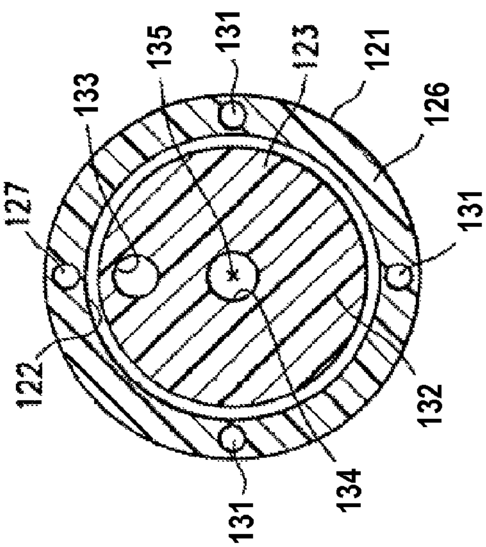

FIG. 13B

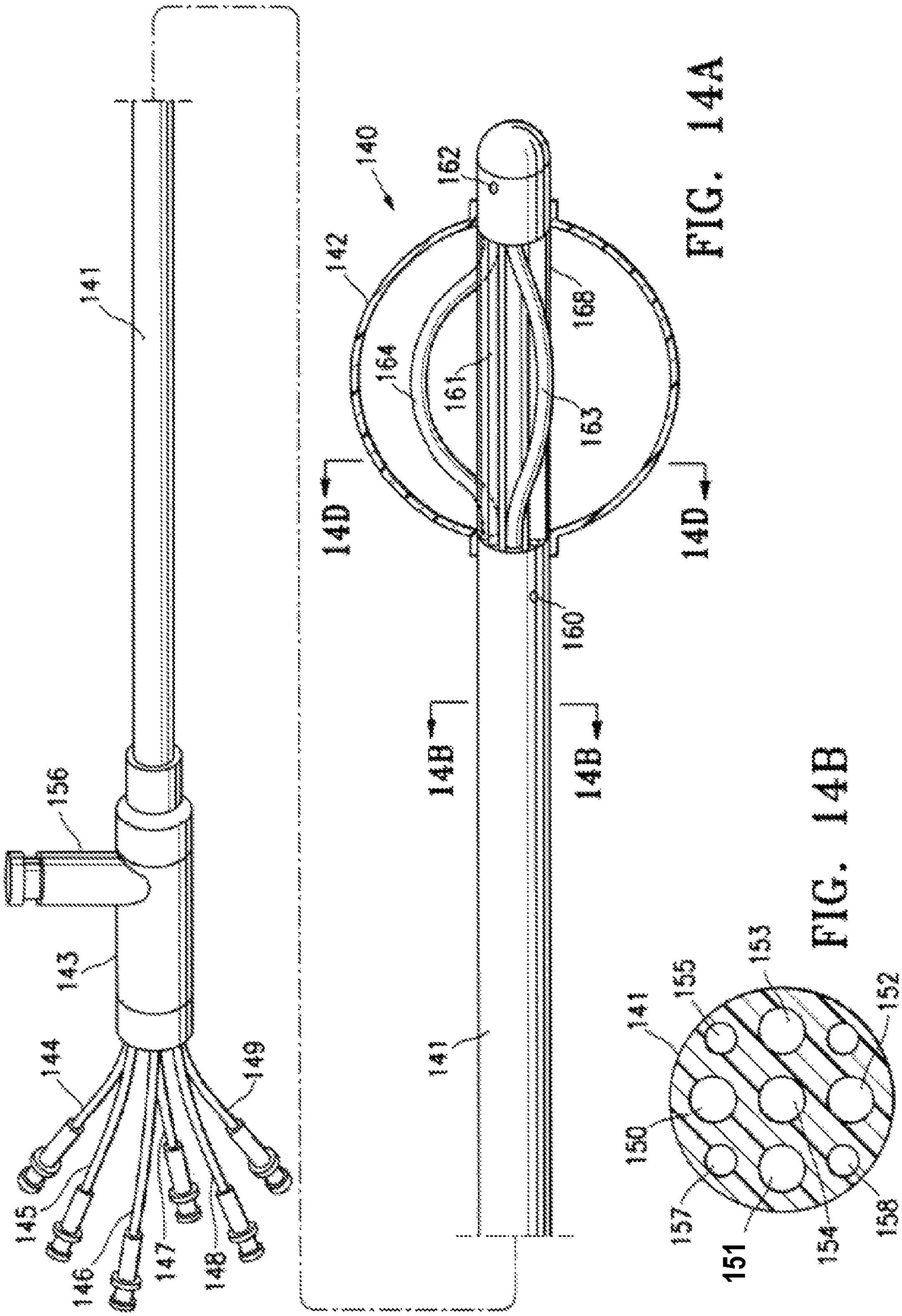

FIG. 14A

FIG. 14B

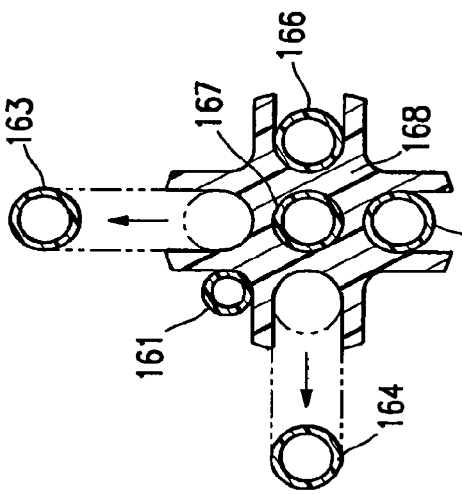

FIG. 14D

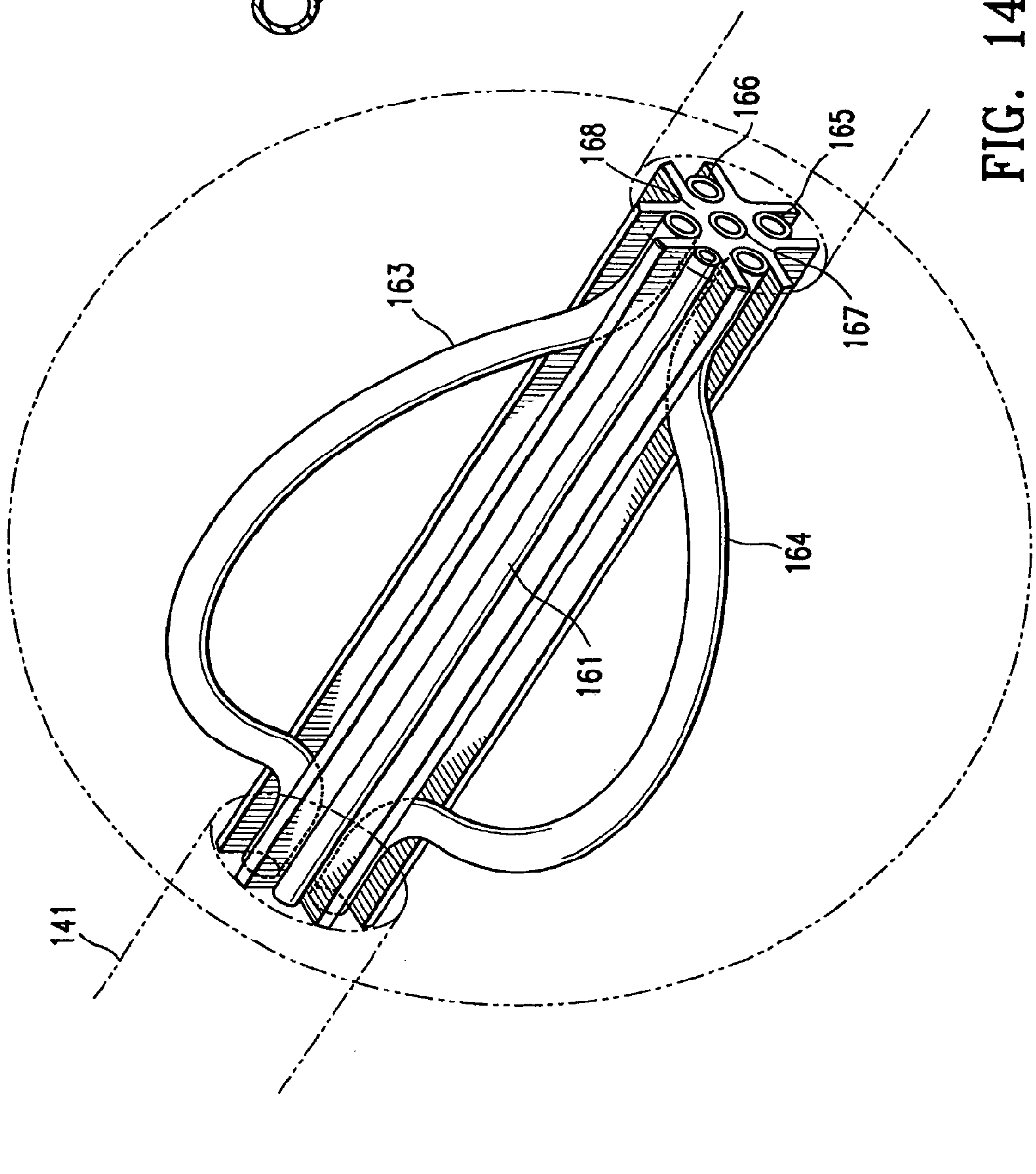

FIG. 14C

BRACHYTHERAPY DEVICE FOR ASYMMETRICAL IRRADIATION OF A BODY CAVITY

RELATED APPLICATIONS

This application is a continuation of application Ser. No. 12/151,154 filed May 2, 2008 now U.S. Pat. No. 8,075,469, which is a continuation of application Ser. No. 11/593,789, filed Nov. 6, 2006, now U.S. Pat. No. 7,465,268, which is a continuation-in-part of Ser. No. 11/283,236, filed Nov. 18, 2005, now U.S. Pat. No. 7,413,539, and which is related to and claims priority from provisional application Ser. No. 60/819,919 filed on Jul. 11, 2006 entitled Radiation Device For A Body Cavity, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

This invention relates generally to the fields of medical treatment devices and methods. In particular, the invention relates to devices and methods for treating tissue surrounding a body cavity, such as a site from which cancerous, pre-cancerous, or other tissue has been removed.

BACKGROUND OF THE INVENTION

In diagnosing and treating certain medical conditions, it is often desirable to perform a biopsy, in which a specimen or sample of tissue is removed for pathological examination, tests and analysis. A biopsy typically results in a biopsy cavity occupying the space formerly occupied by the tissue that was removed. As is known, obtaining a tissue sample by biopsy and the subsequent examination are typically employed in the diagnosis of cancers and other malignant tumors, or to confirm that a suspected lesion or tumor is not malignant. Treatment of cancers identified by biopsy may include subsequent removal of tissue surrounding the biopsy site, leaving an enlarged cavity in the patient's body. Cancerous tissue is often treated by application of radiation, by chemotherapy, or by thermal treatment (e.g., local heating, cryogenic therapy, and other treatments to heat, cool, or freeze tissue).

Cancer treatment may be directed to a natural cavity, or to a cavity in a patient's body from which tissue has been removed, typically following removal of cancerous tissue during a biopsy or surgical procedure. For example, U.S. Pat. No. 6,923,754 to Lubock and U.S. patent application Ser. No. 10/849,410 to Lubock, the disclosures of which are all hereby incorporated by reference in their entireties, describe devices for implantation into a cavity resulting from the removal of cancerous tissue which can be used to deliver cancer treatments to surrounding tissue. One form of radiation treatment used to treat cancer near a body cavity remaining following removal of tissue is "brachytherapy" in which a source of radiation is placed near to the site to be treated.

Lubock above describes implantable devices for treating tissue surrounding a cavity left by surgical removal of cancerous or other tissue that includes an inflatable balloon constructed for placement in the cavity. Such devices may be used to apply one or more of radiation therapy, chemotherapy, and thermal therapy to the tissue surrounding the cavity from which the tissue was removed. The delivery lumen of the device may receive a solid or a liquid radiation source. Radiation treatment is applied to tissue adjacent the balloon of the device by placing radioactive material such as radioactive "seeds" in a delivery lumen. Such treatments may be repeated if desired.

For example, a "MammoSite® Radiation Therapy System" (MammoSite® RTS, Proxima Therapeutics, Inc., Alpharetta, Ga. 30005 USA) includes a balloon catheter with a radiation source that can be placed within a tumor resection cavity in a breast after a lumpectomy. It can deliver a prescribed dose of radiation from inside the tumor resection cavity to the tissue surrounding the original tumor. The radiation source is typically a solid radiation source; however, a liquid radiation source may also be used with a balloon catheter placed within a body cavity (e.g., lotrex®, Proxima Therapeutics, Inc.). A radiation source such as a miniature or micro-miniature x-ray tube may also be used (e.g. U.S. Pat. No. 6,319,188). The x-ray tubes are small, flexible and are believed to be maneuverable enough to reach the desired treatment location within a patient's body. The radiation source is to be removed following each treatment session, or remains in place as long as the balloon remains within the body cavity. Inflatable treatment delivery devices and systems, such as the MammoSite® RTS and similar devices and systems (e.g., GliaSite® RTS (Proxima Therapeutics, Inc.)), are useful to treat cancer in tissue adjacent a body cavity.

However, radiation, chemotherapy, thermal treatment, and other cancer treatments often have deleterious effects on healthy tissue in addition to the desired effects on cancerous tissue. In such treatments, care must be taken to direct the maximum treatment effects to diseased tissue while minimizing its delivery or effects on healthy tissue. For example, radiation treatment may be most effective when only the portion of tissue requiring treatment receives the radiation and where surrounding healthy tissue is unaffected. Tissue cavities typically are not uniform or regular in their sizes and shapes, so that differences in dosages applied to different regions of surrounding tissue, including "hot spots" and regions of relatively low dosage, often result from radiation treatment.

A treatment delivery device for treating tissue adjacent a body cavity has been disclosed in U.S. Pat. No. 6,923,754. This device applies a partial-vacuum or suction to bring tissue towards a radiation source and allows for uniform application of radiation to tissue surrounding a body cavity. An advantage of the present invention is that it allows for the protection of healthy tissue within that body cavity and provides a seal in the passageway leading to the body cavity while treating the desired tissue.

SUMMARY OF THE INVENTION

This invention is generally directed to treating a patient's body cavity or other intracorporeal site (hereinafter collectively referred to as a body cavity) and devices and methods for such treatments. The invention is particularly suitable for treating tissue adjacent to a body cavity formed by the removal of tissue such as in a biopsy or lumpectomy.

More specifically, a device embodying features of the invention has a distal portion with a treatment location which is configured to be asymmetrically deployed within the body cavity so as to be closer to a first portion of tissue surrounding the cavity than a second portion of tissue surrounding the cavity opposite the first tissue portion. The treatment location of the distal portion which includes or is configured to receive a radiation source such as a brachytherapy seed or other irradiating agent for irradiating the first portion of tissue surrounding the body cavity more intensely that the second portion of tissue surrounding the body cavity opposed to the first portion of tissue due to the radiation source being closer to the first tissue portion than to the second tissue portion.

In one embodiment the treatment location having a radiation source is offset or capable of being offset within the body cavity so that tissue of the first portion of the cavity receives more intense radiation treatment than the tissue of the second portion.

This invention is generally directed to treating a patient's body cavity or other intracorporeal site and devices and methods for such treatments. The invention is particularly suitable for treating tissue adjacent to a body cavity such as a cavity formed by the removal of tissue.

More specifically, a device embodying features of the invention has a distal portion with a treatment location which is configured to be asymmetrically deployed within the body cavity and which is configured to receive or which includes a brachytherapy or other irradiating agent for treating tissue surrounding the cavity or other site.

In one embodiment the treatment location having a radiation source is offset or capable of being offset from the central location within the body cavity so that tissue of one portion of the cavity receives more intense radiation treatment than the tissue of an opposing portion.

The invention is generally directed to treating a patient's body cavity by irradiation, and devices and methods for such treatments. The invention is particularly suitable for treating tissue adjacent a patient's body cavity, such as that formed by removal of tissue for a biopsy.

More specifically, a device embodying features of the invention includes a treatment location at a distal portion of the device which is configured to receive or which includes a brachytherapy agent, such as a radiation source and which has a centrally located longitudinal axis. The distal portion of the shaft with the treatment location is deployable within the body cavity so as to provide asymmetrical treatment such as irradiation thereto to tissue surrounding the cavity and is or is capable of being deployed away from the longitudinal axis and closer to one portion of the cavity than an opposed portion.

In one embodiment the distal portion of the device has at least one delivery lumen which is configured to receive a radiation source and which is off-set or capable of being off-set from a central longitudinal axis so that the radiation source is closer to the tissue of the first portion of the body cavity than the tissue of the second portion of the cavity at an opposing side resulting in greater levels of radiation being received by the first tissue portion of the cavity. In this embodiment the device may also have one or more radiation shielding components that provide further control of the radiation emitted from the radiation source, such as described in application Ser. No. 11/593,952 (now U.S. Pat. No. 7,407,476), entitled Tissue Irradiation With Shielding. Off-setting the lumen in which the radiation source is deployed places the radiation source closer to a first tissue portion surrounding the body cavity to provide greater levels of radiation thereto and further away from the second tissue portion surrounding the body cavity at other locations to reduce the level of radiation thereto. The radiation received by the tissue surrounding the body cavity is a function of inverse of the distance (R) from the radiation source squared ($1/R^2$), so even small changes in the location of the radiation source within a body cavity can make a significant impact on the amount of radiation received by tissue in the body cavity or site. In this embodiment the shaft having the distal portion with the treatment location may be deformed to deflect the radiation lumen to an off set location with respect to the central longitudinal axis. An alternative is to provide an asymmetrical cavity filling member that holds the distal portion of the shaft with the treatment location at a desired position within the cavity or body site to provide asymmetrical irradiation to the tissue surrounding the cavity or site. This maybe accomplished with a cavity filling member that is asymmetrical, is mounted asymmetrically on the shaft or is configured to be inflated to an asymmetrical shape. The cavity filling member may have separate chambers which are independently inflated to different sizes so as to develop an asymmetrical shape that results in an off-set of the radiation source.

In another embodiment the device has an outer sheath with an inner lumen and an inner cannula or catheter which is rotatably disposed within the inner lumen of the outer sheath. The cannula or catheter has an inner lumen which is configured to receive a radiation source. The inner lumen receiving the radiation source is off set from a central longitudinal axis of the catheter or cannula, so that rotation of the cannula or catheter within the inner lumen of the outer sheath will adjust the position of a radiation source within the body cavity or site to provide the desired asymmetrical irradiation dose within the cavity.

The elongated shaft may also have one or more radiation shielding components designed to reduce or minimize damaging irradiation of healthy tissue surrounding the body cavity while treating nearby areas having diseased tissue with radiation emitted from the radiation source. The radiation shielding components include one or more radiation shields disposed about a delivery shaft containing the radiation source. Suitable radiation shielding components are described in application Ser. No. 11/593,952 (now U.S. Pat. No. 7,407,476), entitled Tissue Irradiation With Shielding.

A device embodying features of the invention preferably has an enlarged or enlargeable cavity filling member at the treatment location which at least in part fills the body cavity. Preferably, the cavity filling member is inflatable member such as a balloon. The elongated shaft has an inner inflation lumen for directing inflation fluid to the interior of the cavity filling member for its inflation.

The device may also include an inner lumen configured to be in fluid communication with a proximal vacuum source and one or more vacuum ports preferably proximal and or distal to the cavity filling member such as described in U.S. Pat. No. 6,923,754 and application Ser. No. 10/849,410 filed on May 19, 2004, (now U.S. Pat. No. 6,955,641), both of which are assigned to the present assignee. Application of a vacuum within the inner lumen aspirates fluid in the cavity through one or more vacuum ports and the vacuum within the body cavity pulls tissue defining the cavity onto the exterior of the cavity filling member deployed within the cavity. The application of a vacuum may also be employed to aspirate fluids from the cavity or site.

A method for treating a body cavity or other intracorporeal site of a patient includes delivering a treatment agent such as a radiation source to a body cavity to treat the desired tissue while minimizing damaging irradiation of healthy tissues. More specifically, a method for treating a body cavity or intracorporeal site includes providing a device having an elongate shaft with a proximal end, a distal end, and a treatment location in a distal portion of the shaft. The method further includes providing a radiation source configured to be deposited in the treatment location and a radiation shielding component partially encircling the treatment location which is configured to control at least in part the emission of radiation emitted from the treatment location. The device is advanced within the patient until the treatment location of the device is deployed within the body cavity or site and the radiation source is positioned within the treatment location.

The radiation shielding component is positioned to shield portions of the body cavity from radiation emitted from the radiation source.

A patient's skin is susceptible to damage from radiation delivered by isotopes (e.g. seeds) or x-ray catheters in a lumen of a radiation balloon catheter if the radiation source is to close to the skin. Generally, radiation treatments using a radiation balloon catheter is usually not performed on patients where the body cavity (e.g. from a lumpectomy) is less than 5 mm, sometimes less than 7 mm from the patient's skin. Additionally, over inflation of the balloon can thin and stretch the skin. The application of a vacuum to the body cavity can help by pulling the tissue to the balloon and increased cavity to skin surface distances would result. However, in some instances it would still be too thin to treat. The number of potential patient's which are suitable candidates for treatments with the present device is significantly increased due to reducing the potential for skin tissue damage.

Placing patterns of radiation absorbing materials on the surface or within the wall of the balloon would aid in shielding the skin or in other cases, sensitive organs (e.g., heart, lung, ribs, etc.) from unnecessary radiation. Examples include—Mylar with aluminum, balloon coatings with gold, lead, titanium barium and barium sulfate or silver ions incorporated within the balloon wall.

The surface (inside or outside) of the balloon or within the balloon wall may be provided with indicator marks for location or orientation detection during the procedures. For example, dots or lines to help place balloon in appropriate position under CT, x-ray or fluoroscopy. The indicator marks may be radiopaque. Alternatively, or additionally, ultrasound indicators or MRI and direct visual indicators could be incorporated. The indicator marks may extend along the catheter shaft to help with placement of the catheter device during the treatment procedure and the orientation of the off set lumen and shield.

In other embodiments having features of the invention, the radiation shield may be secured to a control rod or band within the catheter device so that the location of the shield may be adjusted. Alternatively, the radiation shield may be secured within or onto the catheter device.

These and other advantages of the present invention are described in more detail in the following written description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view, partially in section, of a brachytherapy device embodying features of the invention including a cavity filling member.

FIG. **2** is a transverse cross sectional view of the device shown in FIG. **1** taken along lines **2-2** which illustrates the device with two inner lumens.

FIG. **3** is a transverse cross sectional view of an alternative device similar to the device shown in FIG. **1** having three lumens.

FIG. **4** is a transverse cross sectional view of an alternative device similar to the device shown in FIG. **1** having 5 lumens.

FIG. **5** is a transverse cross-sectional view of an alternative device having three lumens having circular transverse cross-sections and a pair of opposed arcuate inner lumens for radiation shielding component.

FIG. **6** is a transverse cross-sectional view of a device similar to that shown in FIG. **1** which has a plurality of arcuate lumens with enlarged central portions which allow for the deployment of a radiation shield or a radiation source within the lumens.

FIG. **7** is an elevational view, partially in section, of a distal portion of an alternative design for a brachytherapy device wherein the shaft within the cavity filing member is deformed to place the radiation source closer to one side of the cavity filling member than an opposed site.

FIG. **7A** is an enlarged longitudinal cross-section of the deformed shaft within the cavity filling member.

FIG. **8** is a transverse cross-sectional view of the device shown in FIG. **7** taken along the lines **8-8**.

FIG. **9** is an elevational view of a distal portion of an alternative design for a brachytherapy device wherein the cavity filling member is asymmetric, or inflated to an asymmetric configuration to place the radiation source closer to one side of the body cavity or site.

FIG. **10** is a transverse cross-sectional view of the brachytherapy device shown in FIG. **9** taken along the lines **10-10**.

FIG. **11** is a transverse cross-sectional view similar to that shown in FIG. **10** in which the interior of the cavity filling member is separated into two chambers by a membrane so that each chamber may be inflated, e.g. to different sizes.

FIG. **12** illustrates a shaft formed of a plurality of elongated elements with at least one of the elongated elements having an inner lumen configured to receive a radiation source.

FIGS. **13**A-B illustrate another embodiment having features of the invention which has an outer catheter with a cavity filling member and an inner catheter with an inner lumen which is off set or off settable from a longitudinal axis.

FIG. **14**A is a perspective view, partially in section, of an alternative device which has a plurality of radially extending tubular members for delivery of radiation sources.

FIG. **14**B is a transverse cross-sectional view of the device shown in FIG. **14**A taken along the lines **14**B-**14**B.

FIG. **14**C is a perspective view of a compartmented support member and tubular members which extend through an inflatable member.

FIG. **14**D is a transverse cross-sectional view of the device shown in FIG. **14**A taken along the lines **14**D-**14**D.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to devices and methods for treatment of a patient's body cavity, particularly to deliver asymmetrical radiation into a biopsy cavity or into a cavity left after removal of tissue from the patient's body. Other body sites may also be treated.

FIGS. **1** and **2** illustrate a brachytherapy device **10** embodying features of the invention which has an elongated shaft **11** with a treatment location **12** in a distal portion **13** of the elongated shaft **11**. The elongated shaft **11** has a first lumen **14** which is off set from central longitudinal axis **15** and which is configured to receive a radiation source **16**. The radiation source **16** is disposed at the distal end of pusher rod **17** to facilitate deployment within the treatment location **12**. The elongated shaft **11** also has a second lumen **18** for delivery of inflation fluid to the interior of the cavity filling member **19** through inflation port **20**. The elongated shaft **11** may also have a third lumen **21** shown in phantom to provide a vacuum to a desired location such as vacuum ports **22** and **23** also shown in phantom which are proximal and/or distal to the cavity filling member **19** as described in U.S. Pat. No. 6,923,641 (assigned to the present assignee). The third lumen may also be utilized as an off-set lumen to receive a radiation source in the event the first lumen **14** is not in a desired location when the distal end of the device is placed in the patient and the physician does not wish to rotate the device **10**. The proximal end of the elongated shaft **11** has a multi-arm adapter **24** for delivery of a vacuum, inflation fluid and radiation source as shown. The device **10** may also have one or more radiation shielding components (not shown) to further reduce radiation to tissue which is not to be treated. Suitable radiation shielding components are described in application Ser. No. 11/593,952 (now U.S. Pat. No. 7,407,476), entitled Tissue Irradiation With Shielding which has been assigned to the present assignee.

A body cavity within a patient may be treated with the device **10** by inserting the distal shaft portion **13** into the desired body cavity with the off-set first lumen **14** configured to receive the radiation source **16** being closer to a first tissue portion surrounding the cavity to be treated and farther away from a second tissue portion surrounding the cavity which needs to be protected. A radiation source **16** is advanced within the first lumen **14** until the radiation source is properly positioned within the treatment location **12** (or prepositioned therein). Inflation fluid is delivered to the interior of the cavity filling member **19** so as to at least partially fill the body cavity. A vacuum may be generated about the cavity filling member **19** through vacuum ports **22** and **23** to conform the tissue surrounding the cavity to the exterior of the cavity filling member. The radiation source **16** is maintained at the treatment location **12** for a prescribe period of time, usually less than 30 minutes and typically a few (5-10) minutes. At the end of the treatment time the radiation source may be removed from device **10** or the entire device may be withdrawn from the patient. Preferably, the device is left in place so that further radiation treatments may be performed.

FIG. **3** illustrates an elongated shaft **11***a* of an alternative brachytherapy device which has three off-set lumens **25**, **26** and **27** that are equally disposed about the longitudinal axis **28**. The first off-set lumen **25** may be used as the radiation delivery lumen such as described above for first lumen **14**. The second and third off-set lumens **26** and **27** may be utilized for delivery of inflation fluid to the interior of a cavity filling member (not shown) or for delivery of a vacuum to vacuum ports (not shown) proximal or distal to the cavity filling member as described above. Additionally, a centrally located fourth lumen **29** (shown in phantom) may be provided as an alternative lumen for radiation delivery in the event an off-set location is not needed. The fourth lumen may also be employed as an inflation or vacuum lumen as described above, leaving one of the off-set lumens **26** and **27** to deliver a radiation source in the event the first off-set lumen is not in a desirable location when the device is deployed within the patient's body cavity.

FIG. **4** illustrates an elongated shaft **11***b* of another alternative design of device **10** which has four off set lumens **30-33**, one central lumen **34** which is axially aligned with longitudinal axis **35**. The off set lumens **30-33** and central lumen **34** may be utilized as in the prior embodiments. This embodiment provides additional alternative lumens for delivery of a radiation source (not shown) as described above.

FIG. **5** illustrates yet another elongated shaft **11***c* of an alternative design which has two off set lumens **36** and **37** and a central lumen **38** which have circular transverse cross-sections as shown. The off set and central lumens **36**, **37** and **38** may be utilized as described above. Additionally, at least one arcuate lumen **39** may be provided to facilitate placement of a radiation shield **40** as described in application Ser. No. 11/593,952 (now U.S. Pat. No. 7,407,476) entitled Tissue Irradiation With Shielding. A second arcuate lumen **41** at an opposed position within the shaft **11***c* (shown in phantom) for delivery of a radiation shield in the event the device is not placed in a desired orientation and the physician does not want to rotate the device.

FIG. **6** depicts another elongated shaft **11***d* for an alternative brachytherapy device **10** which has a first arcuate lumen **42** with an enlarged central portion **43**. This first arcuate lumen **42** is design to slidably receive a radiation shielding member **44** and the enlarged central portion **43** is designed to slidably receive a radiation source **45** such as shown in second arcuate lumen **46** with enlarged central portion **47**. A central lumen **48** is axially disposed about the longitudinal axis **49** and may be utilized for delivery of inflation fluid or a vacuum to the distal portion of the device. This design allows for the flexibility of placing either a radiation source or a radiation shielding member on either side of the device. The central lumen **48** may alternatively be positioned off-set within the shaft **11***d*. Other off-set lumens may be provided as described above with respect to the other embodiments.

FIGS. **7**, **7**A and **8** depict an alternative brachytherapy device **50** which has an elongated shaft **51** with a treatment location **52** in a distal portion **53** thereof. The shaft **51** is deformable within the treatment location **52**. The elongated shaft **51** has a first lumen **54** which is configured to receive a radiation source **55** to position a radiation source off set from the longitudinal axis **56**. The radiation source **55** has a standard pusher rod **57** to facilitate placement of the radiation source at the treatment location **52** within the first lumen **54**. The distal shaft portion **53** is deformed, i.e. radially deflected, by pull-wire **58** so that the treatment location **52** is off-set or further off set from the longitudinal axis **56**. The distal end of the pull-wire **58** has an enlarged hub which secures the distal end of the pull-wire within the shaft. The deformation of the distal shaft portion **53** places the radiation source **55** closer to one side of the cavity filling member **60** thereby reducing the radiation to tissue of the opposing side of the cavity. While only one pull-wire **58** is illustrated, multiple pull-wires may be employed about the longitudinal axis **56** to facilitate deformation of the distal shaft portion **53** in multiple directions. Other mechanical structures, may be provided to radially deflect the distal shaft portion **53** away from longitudinal axis **56**. Off-set lumen **61** leads to inflation port **62** for directing inflation fluid to the interior of the cavity filling member **60**. Off-set lumen **63** leads to vacuum port **64** (shown in phantom) proximal to the cavity filling member **60** to generate a vacuum within the body cavity to aspirate fluids and/or to conform surrounding tissue of the body cavity to the exterior of the cavity filling member **60**.

FIGS. **9** and **10** illustrate another brachytherapy device **70** embodying features of the invention. The device **70** has an elongated shaft **71**, a treatment location **72** in distal shaft portion **73**, a first lumen **74** configured to receive radiation source **76**, a second lumen **77** and a third lumen **78** and an asymmetrical cavity filling member **80**. The first lumen **74** is closest to the smaller side **81** of the cavity filling member **80** so that radiation through the smaller side **81** of the cavity filling member **80** to adjacent tissue is greater than the radiation through the larger side **82** to adjacent tissue. The larger side **82** of the cavity filling member **80** is placed next to tissue in which the radiation dose is to be minimized, whereas the smaller side **81** is positioned adjacent to tissue which is to receive a higher dose of radiation. The second and third lumens **77** and **78** may be utilized for vacuum and inflation fluid as discussed above with respect to other embodiments.

FIG. **11** shows an alternative brachytherapy device **90** which has an elongated shaft **91** with three inner lumens. Off set lumens **92** and **93** and centrally disposed lumen **94**. The first off set lumen **92** is for receiving a radiation source as previously described. The second off set lumen **93** may be for vacuum, inflation fluid or as an alternative lumen for a radiation source. The central lumen **94** may be employed for vacuum, inflation fluid or alternatively a radiation source. The device **90** has a cavity filling member **95** which has inner membranes **96** and **97** which separate the interior of the cavity filling member into separate chambers **98** and **99**. Each chamber has separate sources (lumens) for inflation fluid so that one side **100** of the cavity filling member **95** may be inflated to one or more different sizes than an adjacent side **101**. As shown in phantom, the side **100** may be inflated to a smaller size **100***a* or a larger size **100***b*. Adjusting the sizes controls the location of the radiation source within a lumen. With a smaller size **100***a*, the tissue to be treated adjacent to side **100** receives a higher radiation dose than tissue adjacent to side **101** which should be protected and given a smaller radiation dose. Alternatively, when chamber **98** is inflated so that side **100** is of a larger size, the tissue adjacent to side **100** will receive more radiation.

FIG. **12** depicts an elongate shaft **11***e* of an alternative device which comprises a plurality of elongated tubular elements **110**, **111**, **112** and **113**. At least one of the elongated elements **110** has a first inner lumen **114** configured for receiving a radiation source such as described above for the other embodiments. The other elongated elements may also have inner lumens **115-117** for delivery of inflation fluid to a cavity filling member (not shown) on a distal portion of the shaft, for delivery of a vacuum to a vacuum port proximal or distal to the cavity filling member or an additional lumen for receiving a radiation source. The plurality of elements **110-113** may be bundled together by one or more outer straps or bands or by an outer sheath or by a suitable adhesive. The plurality of elongated elements of the shaft may be twisted or braided together. Tubular element **110** (as well as **111-113**) may be radially deflected as depicted in FIG. **7** to position the first inner lumen closer to the first tissue portion surrounding the body cavity than the second tissue portion.

FIGS. **13**A-B illustrate a brachytherapy device **120** which has an outer catheter **121** with an inner lumen **122** and an inner catheter **123** which is configured to be rotatably disposed within the inner lumen **122**. The outer catheter **121** has an inflatable cavity filling member **124** on a distal portion **125** of shaft **126**. The wall of shaft **126** has at least one lumen **127** for directing inflation fluid to the interior of the cavity filling member **124**. The outer catheter **121** also has vacuum ports **128** and **129** proximal and distal to the cavity filling member **124**. The wall of shaft **126** has at least one lumen **131** which is in fluid communication with a vacuum port and preferably two lumens. The inner catheter **123** has an elongated shaft **132** with an offset lumen **133** and may also have a central lumen **134** configured for receiving a radiation source to provide an asymmetrical radiation dose about longitudinal axis **135**.

FIGS. **14**A-**14**D illustrate an alternative device **140** which has an elongated shaft **141**, a cavity filling balloon **142** on the distal portion of the shaft and an adapter **143** on the proximal end of shaft **141**. A plurality of tubes **144-148** extend into the adapter **143** and are in fluid communication with lumens **150-154** respectively within the shaft **141** which are configured to receive radiation sources (not shown) such as those previously described. The device **140** also has an inflation tube **149** which is in fluid communication with lumen **155** that extends to and is in fluid communication with the interior of the balloon **142** to facilitate delivery of inflation fluid thereto. The adapter **143** has a vacuum arm **156** that is in fluid communication with lumens **157** and **158**. Lumen **158** is in fluid communication with proximal vacuum port **160** and lumen **157** is in fluid communication with tubular member **161** which in turn is in fluid communication with distal vacuum port **162**. Radiation delivery tubes **163-167** are in fluid communication with lumens **150-154**. Radiation tube **163** and **164** are radially extended within the interior of balloon **142** in order to be closer to a first tissue portion surrounding a body cavity as previously described. While tubes **163** and **164** are shown as being radially extended within the balloon **142**, one radiation delivery tube or more than two radiation delivery tubes may radially extend within the balloon **142** depending upon the need for a particular treatment.

A compartmented support element **168** extends between the proximal and distal ends of the balloon **142**. The support element **168** shown has nine compartments **170-174** which are designed to receive tubular radiation delivery members **163-167** respectively. The device **140** may be assembled with the radial extension of radiation delivery tubes **144** and **145** fixed as shown or they may be slidable within the catheter shaft **141** so that the radial extension of these delivery tube be effected during the procedure. The radial extension of the radiation delivery tubes will not usually extend to contact the interior surface of the inflated balloon **142**.

The radiation delivery tubes **144-148**, which extend into the adapter **143**, may extend through the lumens in shaft **141** and may form tubes **163-167** which are received by the support member **163**.

All of the radiation delivery tubes which extend through the interior of the balloon **142** would not necessarily be used in a procedure and in fact would probable not be used. However, they would be available for use by the physician if needed, e.g. when the catheter is not in a desired position and rotation of the catheter is not appropriate or desirable. The shaft **141** is shown as a solid shaft having a plurality of passageways. However, the shaft **141** may be made more flexible by utilizing a plurality of tubes which are bundled together form the shaft as shown in FIG. **12**.

The radiation source **16** for the brachytherapy device **10** can include a solid or liquid radiation source. Suitable liquid radiation sources include, for example, a liquid containing a radioactive iodine isotope (e.g., I^{125} or I^{131}), a slurry of a solid isotope, for example, ^{198}Au or ^{169}Yb, or a gel containing a radioactive isotope. Liquid radiation sources are commercially available (e.g., lotrex®, Proxima Therapeutics, Inc., Alpharetta, Ga.). The radiation source **16** preferably includes brachytherapy seeds or other solid radiation sources used in radiation therapy, for example, a radioactive microsphere available from 3M Company of St. Paul, Minn. Microminiature x-ray source may also be utilized. The radiation source **16** may be either preloaded into the device **10** at the time of manufacture or may be loaded into the device **10** before or after placement into a body cavity or other site of a patient. Solid radionuclides suitable for use with a device **10** embodying features of the present invention are currently generally available as brachytherapy radiation sources (e.g., I-Plant.™. Med-Tec, Orange City, Iowa.). Radiation may also be delivered by a device such as the x-ray tube of U.S. Pat. No. 6,319,188. The x-ray tubes are small, flexible and are believed to be capable of being maneuverable enough to reach the desired location within a patient's body.

The brachytherapy device **10** having features of the invention can be provided with a lubricious coating, such as a hydrophilic material. The lubricious coating preferably is applied to the elongate shaft **12** or to the cavity filling member, if one is present, or both to reduce sticking and friction during insertion of a device **10**. Hydrophilic coatings such as those provided by AST, Surmodics, TUA Systems, Hydromer, or STS Biopolymers are suitable.

A device **10** having features of the invention may also include an antimicrobial coating that covers all or a portion of the device **10** to minimize the risk of introducing of an infection during extended treatments. The antimicrobial coating preferably is comprised of silver ions impregnated into a hydrophilic carrier. Alternatively the silver ions are implanted onto the surface of the device **10** by ion beam deposition. The antimicrobial coating preferably is comprised of an antiseptic or disinfectant such as chlorhexadiene, benzyl chloride or other suitable biocompatible antimicrobial materials impregnated into hydrophilic coatings. Antimicrobial coatings such as those provided by Spire, AST, Algon, Surfacine, Ion Fusion, or Bacterin International would be suitable. Alternatively a cuff member covered with the antimicrobial coating is provided on the elongated shaft of the delivery device **10** at the point where the device **10** enters the skin.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. Some details of the brachytherapy devices have not been disclosed. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above in this application as filed are hereby incorporated by reference in their entirety.

What is claimed is:

1. A brachytherapy device for treating tissue surrounding a body cavity of a patient, comprising:

a) a shaft having a proximal end, a distal end, a distal treatment portion proximal the distal end, and a longitudinal axis, the shaft having a plurality of off-set radiation delivery lumens radially off-set from the longitudinal axis that extend into the distal treatment portion, each of the plurality of off-set radiation delivery lumens being configured to receive a radiation source, wherein the plurality of off-set radiation delivery lumens are deformable into an arcuate shape;

b) an expandable member coupled to the shaft to define an expandable volume that surrounds the distal treatment portion, the expandable member being configured to increase space between the expandable member and the plurality of off-set radiation delivery lumens as the expandable member is expanded.

2. A brachytherapy device for asymmetrical irradiation of a body cavity, comprising:

an elongated shaft having a proximal end, a distal end, and a distal shaft portion proximal to the distal end, the elongated shaft having a centrally located longitudinal axis; and

an expandable member coupled to the elongated shaft, the expandable member configured to have a deflated condition and an inflated condition to define an expandable volume at the distal shaft portion, the elongated shaft including:

a plurality of off-set radiation delivery lumens radially off-set from the longitudinal axis having a treatment portion positioned within the expandable volume defined by the expandable member, the plurality of off-set radiation delivery lumens being configured to extend longitudinally at least from the proximal end of the elongated shaft and into the distal shaft portion, with each off-set radiation delivery lumen of the plurality of off-set radiation delivery lumens being configured to selectively receive a radiation source and guide the radiation source into the treatment portion, and wherein the plurality of off-set radiation delivery lumens are deformable into an arcuate shape, and an inflation lumen configured to extend longitudinally at least from the proximal end of the shaft, the inflation lumen being coupled in fluid communication with the expandable volume defined by the expandable member, and configured for connection to an inflation fluid source the expandable member being configured to increase space between the expandable member and the plurality of off-set radiation delivery lumens as the expandable member is expanded.

3. The brachytherapy device of claim **2**, further comprising a central radiation delivery lumen configured to extend longitudinally on the longitudinal axis at least from the proximal end of the shaft and into the distal shaft portion, the plurality of off-set radiation delivery lumens being radially off-set from the central radiation delivery lumen, the central radiation delivery lumen being configured to selectively receive a radiation source.

4. The brachytherapy device of claim **3**, wherein each of the plurality of off-set radiation delivery lumens and the central radiation delivery lumen extends longitudinally across the expandable volume defined by the expandable member.

5. The brachytherapy device of claim **2**, wherein each of the plurality of off-set radiation delivery lumens is located at a respective fixed position relative to the longitudinal axis.

6. The brachytherapy device of claim **2**, wherein each of the plurality of off-set radiation delivery lumens has a respective proximal portion that extends proximally from the proximal end of the elongated shaft.

7. The brachytherapy device of claim **6**, wherein at least the respective proximal portion of each of the plurality of off-set radiation delivery lumens is flexible to facilitate movement of the respective proximal portion relative to the elongated shaft.

8. The brachytherapy device of claim **2**, wherein the plurality of off-set radiation delivery lumens radially off-set from the longitudinal axis consists of three off-set radiation delivery lumens equally disposed around the longitudinal axis.

9. The brachytherapy device of claim **2**, wherein the plurality of off-set radiation delivery lumens radially off-set from the longitudinal axis includes at least three off-set radiation delivery lumens equally disposed around the longitudinal axis.

10. The brachytherapy device of claim **2**, wherein the expandable member is a balloon.

11. A brachytherapy device for asymmetrical irradiation of a body cavity, comprising:

a flexible elongated shaft having a proximal end, a distal end, and a distal shaft portion proximal to the distal end; and

an expandable member coupled to the elongated, the expandable member configured to have a deflated condition and an inflated condition to define an expandable volume at the distal shaft portion, the elongated shaft including:

a central radiation delivery lumen and a plurality of off-set radiation delivery lumens radially off-set from the central radiation delivery lumen having a treatment portion positioned within the expandable volume defined by the expandable member, the treatment portion being configured to be spaced apart from the expandable member as the expandable member is expanded to the inflated condition, each off-set radiation delivery lumen of the plurality of off-set radiation delivery lumens and the central radiation delivery lumen being configured to extend longitudinally at least from the proximal end of the elongated shaft and into the distal shaft portion, with each radiation delivery lumen being configured to selectively receive at least one radiation source and guide the at least one radiation source into the treatment portion, and an inflation lumen configured to extend longitudinally at least from the proximal end of the shaft, the inflation lumen being coupled in fluid communication with the expandable volume defined by the expandable member, the inflation lumen being configured for connection to an inflation fluid source, and wherein the plurality of off-set radiation delivery lumens are deformable into an arcuate shape.

12. The brachytherapy device of claim **11**, wherein each of the plurality of off-set radiation delivery lumens and the central radiation delivery lumen extends longitudinally across the expandable volume defined by the expandable member.

13. The brachytherapy device of claim **11**, wherein each of the plurality of off-set radiation delivery lumens and the central radiation delivery lumen is located at a respective fixed position relative to a longitudinal axis of the flexible elongated shaft.

14. The brachytherapy device of claim **11**, wherein each of the central radiation delivery lumen, the plurality of off-set radiation delivery lumens, and the inflation lumen has a respective proximal portion that extends proximally from the proximal end of the flexible elongated shaft.

15. The brachytherapy device of claim **14**, wherein at least the respective proximal portion of each of the central radiation delivery lumen, the plurality of off-set radiation delivery lumens, and the inflation lumen is flexible to facilitate movement of the respective proximal portion relative to the elongated shaft.

16. The brachytherapy device of claim **11**, wherein the plurality of off-set radiation delivery lumens consists of three radiation delivery lumens equally disposed around the central radiation delivery lumen.

17. The brachytherapy device of claim **11**, wherein the plurality of off-set radiation delivery lumens includes at least three off-set radiation delivery lumens equally disposed around the central radiation delivery lumen.

18. The brachytherapy device of claim **11**, wherein each of the plurality of off-set radiation delivery lumens includes an arcuate portion surrounded by the expandable member.

19. The brachytherapy device of claim **2**, wherein each of the plurality of off-set radiation delivery lumens comprises an enlarged central portion, wherein the enlarged central portion is disposed along a length of each of the plurality of off-set radiation delivery lumens.

20. The brachytherapy device of claim **11**, wherein each of the plurality of off-set radiation delivery lumens comprises an enlarged central portion, wherein the enlarged central portion is disposed along a length of each of the plurality of off-set radiation delivery lumens.

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